SLOVENSKI STANDARD
SIST EN ISO 21647:2009

01-julij-2009

Nadomeġļa:
SIST EN ISO 21647:2005
SIST EN ISO 21647:2005/AC:2006

Elektromedicinska oprema - Posebne zahteve za osnovno varnost in bistvene lastnosti monitorjev dihalnih plinov (ISO 21647:2004, vkljuļno s popravkom A1:2005)

Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 21647:2004, including Cor 1:2005)

Appareils électromédicaux - Prescriptions particulières relatives à la sécurité et aux performances de base des moniteurs de gaz respiratoires (ISO 21647:2004, Cor 1:2005 inclus)

Ta slovenski standard je istoveten z: **EN ISO 21647:2009**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 21647:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21647

April 2009

ICS 11.040.10

Supersedes EN ISO 21647:2004

English Version

Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 21647:2004, including Cor 1:2005)

Appareils électromédicaux - Prescriptions particulières relatives à la sécurité et aux performances de base des moniteurs de gaz respiratoires (ISO 21647:2004, Cor 1:2005 inclus)

This European Standard was approved by CEN on 21 March 2009.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of ISO 21647:2004, including Cor 1:2005 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 21647:2009 by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 21647:2004.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 21647:2004, including Cor 1:2005 has been approved by CEN as a EN ISO 21647:2009 without any modification.

Annex ZA
(Informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 – Correspondence between this European Standard and EU Directives

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
-	6a)	This relevant Essential Requirement is not addressed in this European Standard
-	7.5 (1st paragraph, 2nd sentence and 2nd and 3rd paragraphs)	These relevant Essential Requirements are not addressed in this European Standard
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard
6.1 d)	13.3a)	This relevant Essential Requirement is only partly addressed in this European Standard
6.1 d)	13.2, 13.3 a)	
6.1 aa) to 6.1 hh)	13.2	
6.1 dd)	13.3 f)	The relevant Essential Requirement 13.3 f) is partly addressed
6.1 ee)	13.3 k)	
6.1 ff)	13.3 e)	
6.8.2 aa)	13.4	
6.8.2 cc) 1)	6.8.2 hh), 13.6 b)	
6.8.2 cc) 2)	13.6 a), 13.6 b)	
6.8.2 cc) 3)	13.6 a), 13.6 d), 13.6 i)	
6.8.2.cc) 3	13.6.h)	The relevant Essential Requirement 13.6 h) is partly addressed

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
-	13.6 q)	This relevant Essential Requirement is not addressed in this European Standard
6.8.2 cc) 3) iv)	13.6 a), 13.6 h)	The relevant Essential Requirement 13.6 h) is partly addressed
6.8.2 dd)	13.6 a), 13.6 c)	
6.8.2 ee)	13.6 c)	
6.8.2 ff) to 6.8.2 hh)	13.6 a)	
Table BB.1 also applies.		

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 – Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard
(according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
-	1.1.4	This relevant Essential Requirement is not addressed in this EN
6.2, 101.3	1.5.4	This relevant Essential Requirement is not fully addressed in this EN
-	1.6.1	This relevant Essential Requirement is not completely addressed in this EN; see also reference to IEC 60601-1
-	1.6.2	This relevant Essential Requirement is not addressed in this EN
-	1.6.3	This relevant Essential Requirement is not completely addressed in this EN; see reference to IEC 60601-1
-	3.6.2	This relevant Essential Requirement is not completely addressed in this EN; see reference to IEC 60601-1

INTERNATIONAL STANDARD

ISO 21647

First edition
2004-11-15

Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors

Appareils électromédicaux — Prescriptions particulières relatives à la sécurité et aux performances de base des moniteurs de gaz respiratoires

Reference number
ISO 21647:2004(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 21647 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

This first edition of ISO 21647 cancels and replaces ISO 7767:1997, ISO 9918:1993 and ISO 11196:1995, which have been technically revised.

Introduction

This International Standard is a Particular Standard based on IEC 60601-1:1988, including Amendments 1 (1991) and 2 (1995), hereafter referred to as the General Standard. The General Standard is the basic standard for the safety of all medical electrical equipment used by or under the supervision of qualified personnel in the general medical and patient environment; it also contains certain requirements for reliable operation to ensure safety.

The General Standard has associated Collateral Standards and Particular Standards. The Collateral Standards include requirements for specific technologies and/or hazards and apply to all applicable equipment, such as medical systems, EMC, radiation protection in diagnostic X-ray equipment, software, etc. The Particular Standards apply to specific equipment types, such as medical electron accelerators, high frequency surgical equipment, hospital beds, etc.

NOTE Definitions of Collateral Standard and Particular Standard can be found in IEC 60601-1:1988, 1.5 and A.2, respectively.

To facilitate the use of this International Standard, the following drafting conventions have been applied.

The changes to the text of IEC 60601-1:1988, the General Standard, as supplemented by the Collateral Standards, are specified by the use of the following words.

— "Replacement" means that the indicated clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

— "Addition" means that the relevant text of this Particular Standard is a new element (e.g. subclause, list element, note, table, figure) additional to the General Standard.

— "Amendment" means that existing text of the General Standard is partially modified by deletion and/or addition as indicated by the text of this Particular Standard.

To avoid confusion with any amendments to the General Standard itself, a particular numbering has been employed for elements added by this International Standard: clauses, subclauses, tables and figures are numbered starting from 101; additional list items are lettered aa), bb), etc. and additional annexes are lettered AA, BB, etc.

In this International Standard, the following print types are used:

— requirements, compliance with which can be tested, and definitions: roman type;

— notes and examples: smaller roman type;

— description of type of document change, and test specifications: *italic type*;

— terms defined in Clause 2 of the General Standard IEC 60601-1:1988 or in this Particular Standard: **bold.**

Throughout this Particular Standard, text for which a rationale is provided in Annex AA, is indicated by an asterisk (*).